

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Brian M. Fendly Serial No.: 09/705,579 Filed: November 2, 2000 For: ANTI-ErbB2 ANTIBODIES	Group Art Unit: 1642 Examiner: Christopher Yaen CERTIFICATE OF HAND DELIVERY I hereby certify that this correspondence is being hand delivered to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June <u>3</u> , 2003 <u>R.H. M.</u>
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

☐ **37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

☒ **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

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Serial No. 09/705,579

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☒ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. , filed and relied upon in this application for an earlier filing date under 35 USC §120.

A concise explanation of relevance of the items listed on PTO-1449 is:

- ☒ not given
- ☐ given for each listed item
- ☐ given for only non-English language listed item(s) [Required]
- ☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

Serial No. 09/705,579

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

GENENTECH, INC.

By: _____

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PATENT TRADEMARK OFFICE

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1053R1D1

Serial No.

09/705,579

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Fendly

Filing Date

02 Nov 2000

Group

1642

U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	193	2002/0155527	24.10.02	Stuart et al.			RECEIVED TECH CENTER 1600/2900 03 JUN -3 PM 1:42
	194	5,514,554	07.05.96	Bacus, S.			
	195	5,571,894	05.11.96	Wels, W. et al.			
	196	5,587,458	24.12.96	King, C. et al.			
	197	5,730,977	24.03.98	Ooka et al.			
	198	5,783,404	21.07.98	Koski, R.			
	199	5,804,396	08.09.98	Plowman			
	200	5,846,749	08.12.98	Slamon et al.			
	201	5,856,089	05.01.99	Wang et al.			
	202	5,925,519	20.07.99	Jensen et al.			
	203	5,955,311	21.09.99	Rockwell et al.			
	204	6,165,464	26.12.00	Hudziak et al.			
	205	6,267,958	31.07.01	Andya et al.			
	206	6,270,765	07.08.01	Deo et al.			
	207	6,387,371	14.05.02	Hudziak et al.			
	208	6,395,272	28.05.02	Deo et al.			
	209	6,399,063	04.06.02	Hudziak et al.			
	210	6,407,213	18.06.02	Carter et al.			
	211	6,458,356	01.10.02	Arakawa et al.			
	212	6,512,097	28.01.03	Marks et al.			

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Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No
	213	1,006,194	07.06.00	EPO			
	214	412,116	29.11.95	EPO			
	215	444,181	31.10.01	EPO			
	216	494,135	10.04.96	EPO			
	217	502,812	14.08.96	EPO			
	218	554,441	27.01.99	EPO			
	219	656,367	07.06.95	EPO			
	220	WO 87/07646	17.12.87	PCT			
	221	WO 89/10412	02.11.89	PCT			
	222	WO 91/02062	21.02.91	PCT			
	223	WO 91/05264	18.04.91	PCT			
	224	WO 92/22653	23.12.92	PCT			
	225	WO 93/03741	04.03.93	PCT			

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P1053R1D1	Serial No. 09/705,579	
LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)				Applicant Fendly		
				Filing Date 02 Nov 2000	Group 1642	
FOREIGN PATENT DOCUMENTS						
Examiner Initials	Document Number	Date	Country	Class	Subclass	Translation Yes No
	226	WO 93/16185	19.08.93	PCT		
	227	WO 94/10202	11.05.94	PCT		
	228	WO 96/07321	14.03.96	PCT		
	229	WO 96/16673	06.06.96	PCT		
	230	WO 96/30046	03.10.96	PCT		
	231	WO 96/40789	19.12.96	PCT		
	232	WO 97/00271	03.01.97	PCT		
	233	WO 97/04801	13.02.97	PCT		
	234	WO 98/02463	22.01.98	PCT		
	235	WO 98/18489	07.05.98	PCT		
	236	WO 98/45331	15.10.98	PCT		
	237	WO 99/31140	24.06.99	PCT		
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)						
	238	Burststein et al., "Clinical activity of trastuzumab and vinorelbine in women with HER2-overexpressing metastatic breast cancer" <u>Journal of Clinical Oncology</u> 19(10):2722-2730 (May 15, 2001)				
	239	Chan et al., "Multinational phase II study of navelbine (N) and herceptin (H) as first-line therapy for HER2-overexpressing metastatic breast cancer (HER2+ MBC)" (Abstract #434, SABCS Meeting 2002)				
	240	Dermer, G., "Another anniversary for the war on cancer" <u>Biotechnology</u> 12:320 (1994)				
	241	Filipovich et al., "Chemotherapy with trastuzumab plus vinorelbine in patients with erb-B2 overexpressed tumor is active in metastatic breast cancer" (Abstract #436, SABCS Meeting 2002)				
	242	Jain, R., "Vascular and interstitial barriers to delivery of therapeutic agents in tumors" <u>Cancer and Metastasis Reviews</u> 9:253-266 (1990)				
	243	Kaufman et al., "Phase I trial of Herceptin (H) and navelbine (Nvb) for patients with HER-2/neu (+) advanced breast cancer" (Abstract #431, SABCS Meeting 2002)				
	244	Kim et al., "Inhibition of Vascular Endothelial Growth Factor-Induced Angiogenesis Suppresses Tumour Growth in vivo" <u>Nature</u> 362:841-844 (1993)				
	245	Kim et al., "The Vascular Endothelial Growth Factor Proteins: Identification of Biologically Relevant Regions by Neutralizing Monoclonal Antibodies" <u>Growth Factors</u> 7(1):53-64 (1992)				
	246	Konecny et al., "Therapeutic advantage of chemotherapy drugs in combination with HERCEPTIN against human breast cancer cells with HER-2/NEU overexpression" <u>Breast Cancer Res Treat</u> (Abstract No. 467) 57:114 (1999)				
	247	Li et al., "Monoclonal Antibodies to Recombinant Human Vascular Endothelial Growth Factor" <u>J. Cell. Biochem. Suppl.</u> 015, part F:251 (1991)				
	248	Pietras et al., "Remission of human breast cancer xenografts on therapy with humanized monoclonal antibody to HER-2 receptor and DNA-reactive drugs" <u>Oncogene</u> 17(17):2235-2249 (Oct 29, 1998)				
Examiner				Date Considered		
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.						